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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/631,967 | 08/01/2003 | Alexander Hillisch | GULDE-0002 | 2520 |
| 23599 | 7590 | 11/08/2006 | | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
| | | | EXAMINER BADIO, BARBARA P | |
| | | | ART UNIT 1617 | PAPER NUMBER |

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,967

Applicant(s)

HILLISCH ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5-8,13 and 17-22 is/are allowed.
- 6) ☒ Claim(s) 3,4,9-12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

First Office Action of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The rejection of claim 14 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

4. The rejections of claims 10 and 14 under 35 USC 112, second paragraph are withdrawn.

Art Unit: 1617

5. Claims 3, 4, 9-12 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

(a) Claim 3 recites Y "can be a halogen atom". Apart from "halogen", what is "Y"? It should be noted that parent claim 1 recites "Y stands for a halogen atom". It is suggested that "can be" be rewritten as "is" or "stands for".

(b) Claim 4 recites but does not define formula I.

(c) Claims 9-12 and 14-16 recite but do not define formula I'. In addition, the instant claims are dependent on claim 8 which recites formula I.

Therefore, the claims are indefinite.

Claim Rejections - 35 USC § 103

6. Claims 8-12 and 14-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Schubert et al. (US 5,693,628).

Schubert et al. teaches 11-benzaldoxime-estra-diene derivatives, such as 17 α -chloromethyl-11 β -[4-(hydroximinomethyl)phenyl]-17 β -hydroxy-estra-4,9-diene-3-on, as antigestagenic substances having the same activity as RU 486 at the progesterone receptor but reduced antiglucocorticoid activity (see the entire article, especially col. 3, line 51 –col. 5, line 57; col. 6, lines 12-15; col. 10, lines 9-67). The reference also teaches (a) antigestagens with partial or complete reduction of antiglucocorticoid properties are important for therapy which require therapy over several weeks or

Art Unit: 1617

months and (b) that based on the activity of the compounds, they produce a favorable influence on tissues in which estrogens stimulate growth (see especially col. 3, lines 7-18; col. 10, lines 53-67).

The instant claims differ from the reference by reciting specific methods of using the instant compounds. However, the utilization of an antigestagen in the treatment of each of the methods recited by the instant claims is known in the prior art. For example, (i) inhibition of ovulation, i.e., contraception (see **Schubert et al.**, col. 2, line 41 – col. 3, line 6; **US 2005/0064031**, sections 0001-0003; **US 6,365,585**, col. 3, lines 7-30); (ii) treatment of dysmenorrhea (**US 5,744,464**, col. 1, lines 10-14); (iii) treatment of amenorrhea or treatment of endometriosis (**US 6,365,585**, col. 3, lines 7-30; **US 2005/0064031**, sections 0004-0005) and (iv) dysfunctional bleeding (**US 6,451,780**, Abstract, col. 3, lines 1-10). Therefore, the utilization of the compounds of Schubert et al. in treatment methods as recited by the instant claims would have been obvious to the skilled artisan in the art at the time of the present invention.

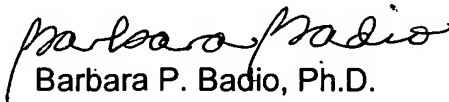
Claims 14-16 further differ from the reference by reciting the administration of the claimed compound(s) in combination with an estrogen for birth control in a female. The utilization of a combination of an antigestagen and an estrogen as contraceptives in females of childbearing age is well known in the art (see for example **US 5,462,949**, col. 1, lines 43-52; **US 6,319,912**, col. 5, lines 56-63). Thus, the claimed invention is prima facie obvious.

Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
November 6, 2006